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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,289	01/02/2004	Syed F.A. Hossainy	50623.363	2385

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT	PAPER NUMBER
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1615

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03/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/751,289	Applicant(s) HOSSAINY ET AL.	
	Examiner CASEY HAGOPIAN	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39,40,42-50 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) 39,40,42-50 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 1/11/2008.

Claims 39, 40, 42-50 and 65-67 are pending. Claims 39, 40 and 42-50 were previously withdrawn. Claims 65-67 are currently amended.

Election/Restrictions

Currently amended claim 65 is directed to non-elected subject matter because applicant has deleted the elected invention, that is, an implantable medical device comprising a primer region comprising unsaturated polymers.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. **Accordingly, claim 65 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.**

Also, this application contains claims 39, 40, 42-50 and 65 which are drawn to an invention nonelected with traverse in the reply filed on 4/28/2005. **A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.**

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 10/17/2007:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 66 and 67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 5 of copending Application No. 11/506,656. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim implantable medical devices comprising a reservoir layer comprising a polymer and a drug and a primer layer free from any drugs comprising a material such as unsaturated polymers, high amine content polymers, acrylates, polymers containing a high content of hydrogen bonding groups, inorganic polymers. Both applications also claim the particular unsaturated polymers, polyester diacrylates, polycaprolactone diacrylates, polytetramethylene glycol diacrylate, polyacrylates with at least two acrylate

groups, polyacrylated polyurethanes, triacrylates, and any combination thereof as well as the particular implantable medical device, a stent. Claim 1 of the copending application is slightly broader in scope and encompasses the subject matter claimed in claim 65 of the instant application. A species always anticipates a genus. Thus, the claims are coextensive in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant is reminded that “the individuals covered by 37 CFR 1.56 have a duty to bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications which are 'material to patentability' of the application in question” (see MPEP 2001.06(b)). Similarly, the prior art references from one application must be made of record in another subsequent application if such prior art references are “material to patentability” of the subsequent application (MPEP 2004, paragraph 9).

Response to Arguments

Applicant's amendments render the rejections of claim 65 moot. Claim 65 no longer reads on elected subject matter, thus the claim has been withdrawn from consideration. As such, all previous rejections of claim 65 have been withdrawn.

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It is noted that the Examiner stated that claim 66 was free of the art, however applicant has amended said claim. Said amendments have broadened the scope of claim 66 which now includes subject matter that reads on previously applied prior art for claims 65 and 67. Thus, the previous art-based rejections made for claims 65 and 67 are now applied to claims 66 and 67 (see *New Rejections* below). Claim 66 is no longer free of the art.

Applicant's arguments with regards to the Double Patenting rejections have been fully considered but they are not persuasive. Applicant argues that "the terminal disclaimer submitted herewith renders the rejections moot". It is respectfully submitted that the Office has no record of said terminal disclaimers for USPN 6,287,285 and USAN 11/506,656. For these reasons, the applicant's arguments are found unpersuasive. It is noted that the subject matter from previously presented claim 65 is now included in amended claim 66, therefore claim 66 has replaced claim 65 in the Double Patenting rejection over USPN 6,287,285 (see *New Rejections* below). Also, the rejection over copending application 11/506,656 has been modified to only include claims 66 and 67 (see *Maintained Rejections* above).

NEW REJECTIONS

The following rejections are new in light of applicant's amendments submitted 1/11/2008:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 66 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Michal et al. (USPN 6,287,285 B1).

Michal '285 teaches an intracorporeal medical device comprising a polymerized base coat on the device and a top coat on the base coat, wherein the top coat comprises a grafting component and a binding component, said grafting component is selected from the group consisting of vinyl, acrylate and allyl compounds and wherein the top coat comprises a therapeutic, diagnostic, or hydrophilic agent, or a complex of a therapeutic, diagnostic or hydrophilic agent and a linking agent (claim 1). Claim 3 discloses polymers as the hydrophilic agent and claim 14 discloses particular devices including stents. Thus, the teachings of Michal '285 render the instant claims anticipated.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 66 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Michal (US 2002/0120326 A1).

Michal '326 teaches a drug delivery system comprising a tubular main body, a biodegradable coating that overlays the tubular main body, one or more drugs that are incorporated in the biodegradable coating and a coating comprising one or more copolymers of ethylene with a carboxylic acid moiety that overlays the biodegradable coating and a primer (claims 34 and 36). Michal '326 also teaches stents and that particular polymers, poly(ethylene-acrylic acid), poly(ethylene vinyl acetate), etc. (paragraph 0025). Thus, the teachings of Michal '326 render the instant claims anticipated.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 66 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Davila et al. (US 2002/0111590 A1).

Davila teaches medical devices including stents comprising a coating, the coating comprising a primer composed of a polymer of vinylidene fluoride and hexafluoropropylene (e.g., an unsaturated polymer) and a topcoat comprising a polymer and a therapeutic agent (paragraphs 0028-0029). Thus, the teachings of Davila render the instant claims anticipated.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 66 and 67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 14 of U.S.

Patent No. 6,287,285 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and the application claim implantable medical devices including stents comprising a primer coat and a top coat, the primer coat can contain an acrylate and the top coat can contain a polymer and a drug. Thus, the claims are coextensive in scope.

Conclusion

All claims have been rejected; no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Examiner, Art Unit 1615

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1615